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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,894	01/09/2002	Jinrui Shi	1286	5731

27310 7590 12/29/2004

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EXAMINER

BAUM, STUART F

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/042,894

Applicant(s)

SHI ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 6-11, 13-21 and 47-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-11, 13-21, 47-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. The amendment filed 10/4/2004 has been entered.
2. Claims 1-4, 6-11, 13-21, 47-68 are pending.  
  
Claims 5, 12, and 22-46 have been canceled.  
  
Claims 47-68 have been newly added and are drawn to the elected invention, which includes SEQ ID NO:7 encoding SEQ ID NO:8.
3. Claims 1-4, 6-11, 13-21, 47-68 are examined in the present office action.
4. Rejections and objections not set forth below are withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

### ***Claim Objection***

6. Claims 19 and 20 are objected to for reciting "of" before the recitation "phytate".

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-4, 6-11, 13-21, and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in the rejection.

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Claim 1 is indefinite for reciting "wherein the polynucleotide has IPPK activity". It is unclear how a polynucleotide can have IPPK activity.

***Written Description***

8. Claims 1-4, 6-11, 13-21 remain rejected and claim 47 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 6/3/2004. Applicant's arguments filed 10/4/2004 have been fully considered but they are not persuasive.

Applicants assert that the claimed invention does adequately describe the method for modulating inositol polyphosphate kinase (IPPK) activity and a method of decreasing the level of phosphorous thereby fulfilling the written description requirement (page 11, 1<sup>st</sup> full paragraph). Applicants contend that the instant specification provides specific methods and a complete written description for the polynucleotides and polypeptides of the claimed invention (page 12, 1<sup>st</sup> full paragraph). Applicants assert the specification does describe a representative number of cDNAs, defined by nucleotide sequence and clearly identify a maize IPPK protein for one of ordinary skill in the art (page 12, 3<sup>rd</sup> full paragraph). Applicants contend that they have taught twelve species of the polynucleotides and polypeptides in species of the polynucleotides and polypeptides in SEQ ID NOS: 1, 3, 5, 7, 9, 11, 13, 15, 17, 20, 22, 24 and SEQ ID NOS: 2, 4, 6, 8, 10, 12, 14, 16, 21, 23, 25, 29-37, respectively (page 13, top paragraph).

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The Office contends that the written description rejection is for claims drawn to sequences that exhibit less than 100% sequence identity with SEQ ID NO:7 or for sequences that encode a protein that exhibits less than 100% amino acid identity with SEQ ID NO:8. The Office acknowledges Applicants' list of SEQ ID NO's as recited above, but Applicants have not disclosed if all the sequences encode a protein with the same activity as SEQ ID NO:8, and have the same substrate specificity as the protein of SEQ ID NO:8. Applicants disclose "IPPK proteins are a class of proteins in inositol phosphate metabolism that are all involved in the phosphorylation of their appropriate inositol phosphate substrate, including but not limited to IP2, IP3, IP4, using ATP as the phosphate donor" (page 21, lines 16-18 of the application). Applicants also have not disclosed conserved domains of the genus of claimed polynucleotides having at least 80% sequence identity compared to the full-length of sequence of SEQ ID NO:7.

### *Enablement*

9. Claims 1-4, 6-11, 13-21 remain rejected and claims 47-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 6/3/2004. Applicant's arguments filed 10/4/2004 have been fully considered but they are not persuasive.

Applicants contend that it would be unreasonable to require Applicants to detail every permutation of the invention (page 14, 1<sup>st</sup> full paragraph). Applicants assert that they have in

fact provided several points of specific guidance with respect to modification of disclosed sequences (page 14, 2<sup>nd</sup> full paragraph).

The Office acknowledges that Applicants are not required to disclose every embodiment of Applicants' invention. But, in the present Application, Applicants have not disclosed a single embodiment of their invention. Given the unpredictability of modifying phytate levels, or the unpredictability of determining if a nucleic acid exhibiting at least 80% sequence identity to SEQ ID NO:7 will encode a protein with the same activity as the protein of SEQ ID NO:8, undue trial and error experimentation would be required by one skilled in the art to practice the claimed invention, as stated in the previous office action mailed 6/3/2004.

Applicants contend that they do teach modulation of SEQ ID NO:7. Applicants contend that they do teach methods that can be used to modify gene expression (page 14, 3<sup>rd</sup> paragraph to page 15, 2<sup>nd</sup> paragraph). Applicants state, "The test for enablement is not whether experimentation is necessary, but rather if experimentation is necessary, whether it is undue." Applicants contend that in the present case, the experimentation required is routine and has been well described in the specification (pages 36-53) (page 15, 4<sup>th</sup> paragraph). Applicants state "the social contract of patents requires full disclosure of the invention in return for a right to exclude others from making, using, or selling such invention. In this case the Applicants have fulfilled their obligation by disclosing the full-length SEQ ID NO: 7, a polynucleotide coding for an IPPK protein, a vector, host cell and plant transformed therewith and a method for modulating inositol polyphosphale kinase activity." (page 16, bottom paragraph).

The Office contends that Applicants have only provided prophetic examples of transforming a plant with any of Applicants' isolated sequences and Applicants have disclosed

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methods that can be used to assay the transformed plants for the desired phenotype. The Office acknowledges that some experimentation is routine, but in the present application, no guidance is given as to which sequences are operable given Applicants' own admitted statement that "IPPK proteins are a class of proteins in inositol phosphate metabolism that are all involved in the phosphorylation of their appropriate inositol phosphate substrates, including but not limited to IP2, IP3, IP4, using ATP as the phosphate donor" (page 21, lines 16-18). Given the complexity of the phytate pathway, Applicants have not demonstrated that transforming a plant with SEQ ID NO:7 encoding SEQ ID NO:8 or sequences that exhibit 80% sequence identity with SEQ ID NO:7, will affect or modify phytate synthesis.

Applicants state "The present claims adequately enable the claimed invention as the structure has been provided to those skilled in the art by further exhibiting an 80% sequence identity with SEQ ID NO:7." (page 15, bottom paragraph).

The Office contends that Applicants have not disclosed any sequence exhibiting 80% sequence identity with SEQ ID NO:7 or any sequence exhibiting 80% sequence identity with SEQ ID NO:7 that encodes a protein with the same activity as the protein of SEQ ID NO:8.

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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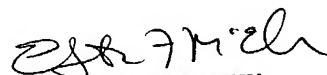
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.  
Patent Examiner  
Art Unit 1638  
December 20, 2004

  
ELIZABETH MCELWAIN  
PRIMARY EXAMINER